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**U.S. Announces Interim Plan to Help Poor Countries fight HIV/AIDS  
and other Health Crises in Absence of WTO Consensus**

*United States Calls on Other WTO Members to Join in Individually Implementing  
the Doha Declaration on the TRIPS Agreement and Public Health*

WASHINGTON - The United States today announced an immediate practical solution to allow African and other developing countries to gain greater access to pharmaceuticals and HIV/AIDS test kits when facing public health crises. The U.S. pledged to permit these countries to override patents on drugs produced outside their countries in order to fight HIV/AIDS, malaria, tuberculosis, and other types of infectious epidemics, including those that may arise in the future.

In the November 2001 Doha trade negotiations, Ministers affirmed that global trade rules permit compulsory licensing of drugs for such domestic health emergencies. One issue left remaining was how to enable poor countries without domestic production capacity to import under compulsory license from third countries drugs needed for HIV/AIDS, malaria, tuberculosis, and other infectious epidemics.

Negotiations in the World Trade Organization (WTO) have been unable to forge a consensus around a new multilateral rule to deal with this situation. Some WTO members and advocacy organizations sought to expand the targeted "poor country epidemic" focus of Doha to allow much wealthier countries to override a wide range of drug patents, for example, Viagra. This approach could seriously undermine the WTO rules on patents that provide incentives for development of new pharmaceutical products, including those to treat diseases of a non-epidemic nature.

The United States will continue to work with other WTO Members to try to find a solution within the WTO. In the meantime, the United States will implement the Doha Declaration by pledging not to challenge any WTO Member that breaks WTO rules to export drugs produced under compulsory license to a country in need, and called on others to join the United States in this moratorium on dispute settlement.

"The United States has worked intensively to find a solution that will provide life-saving drugs to those truly in need, and will continue to work towards that end," said U.S. Trade Representative Robert B. Zoellick. "We urge others to join us in this moratorium to help poor countries get access to emergency life-saving drugs."

### **Interim Measure by the United States Government**

At Doha, Ministers affirmed their commitment to the TRIPS Agreement and confirmed Members' ability to use the flexibility in the Agreement, including the ability to override patents, to address public health crises.

However, many least-developed countries, for example in Africa, and some developing countries, lack sufficient manufacturing capacity in the pharmaceutical sector to make effective use of compulsory licensing as currently provided by the TRIPS Agreement. The interim solution that the United States is announcing today is designed to help those countries combat HIV/AIDS, malaria, tuberculosis, and other infectious epidemics of comparable gravity and scale, including those that may arise in the future, by enabling them to treat these diseases by importing drugs from other WTO Members under the compulsory licensing rules of the TRIPS Agreement. Such infectious diseases would include, for example, ebola, African trypanosomiasis, cholera, dengue, typhoid, and typhus fevers.

The United States expects that all countries will cooperate to ensure that the drugs produced are not diverted from countries in need to wealthier markets.

The United States remains committed to finding a workable, transparent, sustainable, and legally certain solution that will fulfill the Doha Declaration directive as soon as possible. We encourage all countries to reflect on the original purpose of the Doha Declaration and to work for a solution that is consistent with it.

This special measure will not apply to developed country Members of the WTO or those developing economy Members classified by the World Bank as high income countries - Barbados, Brunei, Cyprus, Hong Kong, Israel, Kuwait, Liechtenstein, Macao, Malta, Qatar, Singapore, Slovenia, Taiwan, and the United Arab Emirates. These countries have sufficient production capacity in the pharmaceutical sector or sufficient financial resources to address such public health problems and thus do not need to import under compulsory licenses.

After a year of intensive negotiations, WTO Members have not been able to reach a consensus to implement the remaining elements of the Doha Declaration on the TRIPS Agreement and Public Health because some countries insisted that the solution cover all health problems, including non-emergencies. Further, some Members have insisted that the limited exception be available to all countries regardless of their manufacturing capacities or financial resources. This element of the Doha Declaration was intended to focus international action on the grave public health crises afflicting the poor and to assist countries lacking capacity and resources to obtain access to needed medicines for infectious epidemics. Unless WTO Members focus on infectious epidemics and truly needy countries, the solution called for at Doha will not benefit those for which it was intended.

### **Background:**

The United States has been, and remains, committed to the Doha Declaration of the TRIPS Agreement and Public Health. Throughout the process leading up to, and following, Doha, the United States has sought to address the problems of those countries most in need:

- Prior to the Doha Ministerial last year, the United States recognized the crisis situation resulting from the HIV/AIDS epidemic in sub-Saharan Africa, and announced its willingness to forgo any challenge to countries that needed to override patents to address HIV/AIDS. Unfortunately, this proposal was not accepted by certain Members.
- Further, the United States proposed an extension for all least-developed WTO Members until 2016 with regard to their obligations relating to all pharmaceutical patents, which was adopted by the WTO in 2002.
- The United States remains the largest bilateral donor of HIV/AIDS assistance, providing 45 percent of all international spending on AIDS. In fiscal year 2003, President George Bush has requested \$1.3 billion to combat HIV/AIDS internationally. This is an 82 percent increase over the 2001 appropriations. The President has pledged \$500 million to the Global Fund to combat the international scourge of HIV/AIDS, malaria and tuberculosis, and the President announced a new \$500 million International Mother and Child HIV Prevention Initiative that seeks to prevent the transmission of HIV/AIDS from mothers to infants and improve health care delivery in Africa and the Caribbean.

Several U.S. pharmaceutical companies have formed partnerships with African countries and are working together to address many of the problems related to providing treatment to those in need. Their policies include the sale of critical medicines at very low prices, as well as the building of an improved infrastructure for getting these medicines to those in need. More than 50 percent of all new medicines are invented in the United States. Therefore, we recognize that the solution both to today's health problems - and tomorrow's - in terms of new medicines, will likely come from U.S. companies.

At the Doha Ministerial, Ministers acknowledged the serious public health crises afflicting Africa and other developing and least-developed countries, especially those resulting from HIV/AIDS, malaria, tuberculosis and other infectious epidemics. Ministers agreed on the need for a balance between the needs of poor countries without the resources to pay for cutting edge pharmaceuticals and the need to ensure that the patent rights system which provides the incentives for continued development and creation of new lifesaving drugs is promoted. One major part of the Doha Declaration was agreement to provide an additional ten-year transition period (until 2016) for least developed countries, as proposed by the United States and agreed upon by all WTO Members.

Paragraph 6 of the Doha Ministerial Declaration on the TRIPS (Trade-Related Aspects of Intellectual Property Rights) Agreement and Public Health recognizes that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement in order to address these health problems. WTO Ministers directed the TRIPS Council to find a solution to this problem and to report to the General Council before the end of 2002.

Under current WTO patent rules, a country is free to override a patent, under certain conditions, to allow production of the patented product in its domestic market. This is commonly referred to as “compulsory licensing.” The Doha Declaration affirmed that Members may use compulsory licensing to address public health crises. However, under current WTO rules, products produced under compulsory license generally cannot be exported to other WTO Members. The U.S. solution is intended to eliminate this export restriction so medicine can be supplied to countries most in need that cannot manufacture their own pharmaceuticals.

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